

Regulation 61-120 – South Carolina Immunization Registry Frequently Asked Questions (FAQ)

08/01/2013

1. What is the South Carolina Immunization Registry?

The registry is a data system for the collection, storage, and dissemination of information on immunizations administered in South Carolina.

2. What are the benefits of an immunization registry?

A statewide registry has benefits for both the patient and the provider. A registry consolidates the vaccination history for patients who visit multiple providers. Having all immunizations in one system reduces over and under immunization.

3. Is it mandatory to report administered immunizations to the South Carolina Immunization Registry?

Yes; however, reporting requirements are being phased in over a three-year period, with the first phase taking effect January 1, 2014. As of January 1, 2017, all immunizations administered in South Carolina must be reported to the registry. The statute establishing a mandatory immunization registry, SC Code Section 44-29-40(B), may be found [here](#). Immunization Registry Regulation 61-120 may be found [here](#).

4. When was the regulation effective?

May 24, 2013

5. To whom does the regulation apply?

The regulation applies to the following healthcare providers if they provide immunizations in South Carolina:

- Doctor of Medicine
- Doctor of Osteopathy
- Advanced Practice Registered Nurse
- Physician Assistant
- Doctor of Pharmacy
- Registered Pharmacist

These immunization providers must assure that all immunizations are being reported to the registry either by themselves or the entity they work for.

6. Who is an immunization provider?

An individual healthcare provider licensed, certified, registered or otherwise authorized by law to provide immunizations, and an organization, facility, or other entity that provides immunizations through such individual providers. Some examples of possible immunization providers are doctors, advanced practice registered nurses, physician assistants, pharmacists, hospitals, emergency rooms, urgent care centers, nursing homes, student health centers, Federally qualified health centers (FQHC), and medical practices, among others.

7. What is the purpose of immunization registry registration?

The purpose of the immunization registry registration is to identify all immunization providers in South Carolina.

8. Are immunization providers required to register individually?

No. An immunization provider that is a facility or business entity administering vaccines through employees, agents, or contractors may register in its own name, and the employees, agents, and contractors of such facilities or business entities need not register individually. An immunization provider that is a business entity with multiple locations may register once as a single provider for more than one location. Individual

immunization providers who practice in a group or with a facility or business entity may register individually or in the name of the group or facility or business entity.

9. Are current immunization providers who already submit data either via direct data entry or electronic data submission required to register?

Yes. All immunization providers in South Carolina are required to register.

10. Are current Vaccines for Children (VFC) providers required to register?

Yes. All immunization providers in South Carolina are required to register. Since VFC providers already have a SCI PAS account, the Electronic Signature Authority (ESA) will need to access the system to complete the registry registration.

11. What is the deadline for registration for existing immunization providers?

Existing immunization providers shall register with the Department within ninety (90) days from the effective date of the regulation, which is August 24, 2013.

12. What happens if an immunization provider fails to register by August 24, 2013?

The immunization provider will need to register immediately.

13. What is the deadline for registration for NEW immunization providers?

New immunization providers, such as health care professionals and entities licensed or organized after the effective date of this regulation, shall register with the Department before administering any immunization for which reporting is required under the implementation schedule in this regulation.

14. Are out-of-state immunization providers who administer immunizations in South Carolina required to comply with the regulation?

Yes. All immunizations administered in South Carolina must be reported.

15. Are out-of-state immunization providers who administer immunizations in other states to South Carolina residents required to comply with the regulation?

No. Immunization providers may register and report voluntarily. Out-of-state immunization providers who register voluntarily are subject to and must comply with the provisions of the regulation governing permitted uses and disclosures of registry information and compliance and enforcement as fully as if located in and administering immunizations in South Carolina.

16. Are healthcare providers who do not administer immunizations required to register?

Providers who do not administer immunizations will not be required to register; however, any such provider who wishes to administer immunizations must register before administering immunizations in the same manner as a new immunization provider. While registration is not required, immunization providers who do not administer vaccines may register for access to the registry to search immunization records for their patients. These immunization providers and their authorized users are subject to and must comply with all provisions of the regulation applicable to immunization providers and authorized users and may access and use registry information for permitted uses and disclosures.

17. What is the next step following immunization provider registration?

DHEC staff will make contact with the immunization provider following registration to begin the enrollment processes for direct data entry and electronic data submission reporting methods. The enrollment process will include the completion of the SC Immunization Registry Terms of Use and Registry User Confidentiality Agreement, if applicable. Once these documents have been submitted to and processed by DHEC, DHEC training staff will contact each immunization provider for training on reporting to the immunization registry based on the order the registration was received.

18. Who is an authorized user?

An authorized user is an employee of an immunization provider who has been identified during the enrollment process as a user of the registry.

19. What are the authorized user's responsibilities concerning registry access?

All authorized users shall maintain the confidentiality of their individual access codes and passwords for the immunization registry, and shall not share or exchange such codes with any other person, regardless of whether or not that other person is an authorized user.

20. Is training required to use the SC Immunization Registry?

Authorized users will complete training under schedules established by DHEC. A variety of training methods will be used depending on how the immunization provider plans to report to the registry. DHEC staff will contact each immunization provider for training on reporting to the immunization registry based on the order registration was received.

21. Are legal documents required for SC Immunization Registry access?

Yes. Immunization providers and authorized users must enter into and comply with user agreements specifying terms of use and confidentiality and other obligations. A breach of a user agreement is a violation of the regulation.

22. When should an immunization provider report a user's termination or leaving employment for any reason?

The immunization provider must notify DHEC within fifteen (15) business days after an authorized user is terminated or leaves employment for any reason so their access to the immunization registry can be terminated.

23. When must a provider begin reporting administered immunizations?

January 1, 2014.

24. What is the implementation schedule?

Immunization providers will enter all immunizations into the registry on the following schedule, according to the date of administration and date of birth of the immunized patient:

- All immunizations administered after December 31, 2013 to children born after December 31, 2013 (less than one year of age), and to adults born before 1946 (67 years of age and older);
- All immunizations administered after December 31, 2014, to children born after December 31, 2008 (6 years of age and younger), and to adults born before 1950 (64 years of age and older);
- All immunizations administered after December 31, 2015, to children born after December 31, 2003 (12 years of age and younger), and to adults born before 1961 (54 years of age and older);
- All immunizations administered after December 31, 2016.

Immunizations administered before the designated dates are not required to be entered in the registry, but may be entered voluntarily.

25. How long do I have to report administered immunizations?

Immunization providers shall report all immunizations administered to the registry within ten (10) business days of administration.

26. How do I report immunizations to the Registry?

Immunizations shall be reported in a standard electronic format (i.e., direct data entry, electronic data submission or SCHIEx, or other method specified by DHEC).

27. What are the minimum data elements required for reporting to SC Immunization Registry?

For each immunization administered, immunization providers shall report:

- The date of the immunization
- Specific type of vaccine given
- Patient's first and last name
- Patient's gender
- Patient's date of birth
- Name of the registered immunization provider
- Other data as needed to comply with federal requirements

Other recommended data elements to help confirm identification of patients already in the registry include:

- Patient's medical record number
- Patient's birth information
- Patient's birth order, if a multiple birth
- Mother's name
- Mother's maiden name
- Patient's address
- Patient's telephone number

28. Are immunizations administered to employees reported to the SC Immunization Registry?

Yes. All immunizations administered in South Carolina are required to be reported regardless of the recipient and/or reason.

29. Can an immunization provider or patient opt out of reporting to the SC Immunization Registry?

No.

30. What are the permitted uses and disclosures of immunization registry information?

Information in the immunization registry is confidential and shall be made available only to registered immunization providers through their authorized users. Immunization providers who have registered for access to the registry may obtain information from the registry pertaining only to their own patients.

31. Does HIPAA apply to immunization information submitted to the SC Immunization Registry?

HIPAA allows disclosure of immunization information to the Registry as a disclosure required by law. DHEC, in operating the Registry, is not a covered entity under HIPAA because it is acting as a public health authority. Nevertheless, the immunization information in patient records of immunization providers remains subject to HIPAA, even though it has been reported to the Registry. Information in the Registry is confidential under South Carolina law and its use and disclosure is restricted by regulation.

32. What are the compliance and enforcement requirements?

Immunization providers shall make immunization records available within a reasonable time to authorized representatives of DHEC for inspection upon request. For a violation of the regulation, DHEC may:

- Require an immunization provider or an authorized user to attend registry training;
- Suspend or revoke access to the registry; or
- Assess civil penalties as authorized by Section 44-1-150, S.C. Code of Laws, 1976, as amended.

A DHEC decision regarding the violation may be appealed by an immunization provider or authorized user pursuant to applicable law.